UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 1 CASES**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE CERTAIN OPINIONS OF ALAN GARELY, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Ethicon") submit this memorandum of law in support of their motion to exclude certain opinions of Alan Garely, M.D.[1]

INTRODUCTION

Dr. Garely is a pelvic surgeon and urogynecologist in New York who has experience performing abdominally placed mesh repairs for prolapse as well as native-tissue prolapse repairs, and he has experience in removing transvaginal mesh. However, he has limited experience implanting transvaginal mesh grafts to treat pelvic organ prolapse, and he has never implanted Prolift or Prolift +M. Exh. B, Rule 26 Expert Report of Alan D. Garely, M.D., Prolift ("Rep.") at 5-6. Plaintiffs hope to elicit testimony from Dr. Garely that is well beyond his expertise, such as opinions related to adequacy of product warnings, opinions as to design and biocompatibility of the meshes in Prolift and Prolift +M, and the knowledge and state of mind of the parties. Moreover, many of his general causation opinions are unreliable, lacking in

[1] A list of all Wave 1 cases in which Dr. Garely has been identified as an expert is attached as Exhibit A to the accompanying Motion.

acceptable methodology or scientific support, and are thus inadmissible under Federal Rule of Evidence 702, *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Specifically, the Court should preclude Dr. Garely from testifying about:

- **Opinions regarding Ethicon's knowledge, state of mind and alleged bad acts**. This Court has consistently prohibited improper state-of-mind or legal-conclusion testimony, and should do so in regards to Dr. Garely's proposed testimony as identified herein.

- **Opinions regarding alleged inadequate product warnings.** Dr. Garely cannot substantiate any experience in preparing product warnings, and is admittedly unfamiliar with federal regulations governing product IFU documents.

- **Opinions that amount to nothing more than historical commentary.** In referencing and reciting the contents of Ethicon's internal documents, Dr. Garely is acting as Plaintiffs' advocate rather than expert.

- **Opinions related to FDA regulatory process and requirements.** Dr. Garely admits he has no expertise in regulatory issues.

- **Opinions that require biomaterials or medical device design expertise.** Dr. Garely admitted at his deposition that he has no biomaterials expertise.

- **Opinions regarding alleged safer alternative designs that have no reliable basis.** Dr. Garely fails to provide any safer alternative design to Prolift and Prolift +M.

LEGAL ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *1-3 (S.D. W. Va. July 8, 2014). The Supreme Court's decision in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), precludes "engagement of 'expert' witnesses whose intended role is more to argue the client's cause from the witness stand than to bring the fact-finder specialized knowledge or expertise that would be helpful in resolving the issues of fact presented by the lawsuit." *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 538 (S.D.N.Y. 2004). Plaintiffs seek to do precisely that through the testimony of Dr. Garely. While Dr. Garely may

be qualified to render opinions about pelvic surgery, he has no specialized knowledge or expertise that would substantially assist the jury as it relates to other areas.

I. The Court should exclude Dr. Garely's opinions about Ethicon's knowledge, state of mind, and alleged bad acts.

Throughout his Report, Dr. Garely claims to have knowledge of what risk information supposedly was available to Ethicon and whether Ethicon acted reasonably in its warnings conduct. These claims are based on mere speculation and the testimony of others. Examples set forth in Dr. Garely's expert Report includes the following:

- In its IFU as well as its training and marketing materials, Ethicon made misleading representations to physicians that were contrary to its own internal documents which showed information known to or, at a minimum, available to Ethicon. Exh. B, Rep. at 22.

- In its Patient Information Brochure for the Prolift kits, Ethicon claimed that '[Prolift] allows for the restoration of sexual function by restoring vaginal anatomy,' a claim which is contrary to data from its own studies and to information from a number of sources, including one of the company's own medical directors. *Id.* at 23.

- The IFU statement that '[t]he bi-directional elastic property [of the mesh] allows adaptation to various stresses encountered in the body,' is also misleading. Ethicon never conducted testing nor studies to determine the 'various stresses encountered in the [female pelvis],' so there is no factual basis for any such statement. Also . . . Ethicon's internal documents demonstrate that the mesh was too strong, was 'over-engineered,' and was too stiff and inflexible for use in the female pelvis. *Id.*

- Despite being supplied this information by the director of the study, who also happened to be one of the inventors of the Prolift kits, Ethicon never provided any such warning or information to doctors nor indicated in the labeling any limitation on the use of the Prolift kits relative to the grade or severity of prolapse. *Id.* at 24.

- Ethicon's Medical Director acknowledged that other than a generic reference to 'pain,' the specific risks of painful shrinkage, scarification and contraction of the mesh arms were not included in any warning. *Id.* at 27-28.

There is nothing about Dr. Garely's training and experience as a pelvic surgeon that affords him special expertise or clairvoyance that would somehow enable him to testify about

Ethicon's state of mind. *See, e.g.*, *In re Diet Drugs Prods. Liab. Litig.*, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000) (precluding the plaintiffs' experts from testifying as to the defendants' intent); *In re Rezulin*, 309 F. Supp. 2d at 547 ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony"); *BorgWarner, Inc. v. Honeywell Int'l, Inc.*, 750 F. Supp. 2d 596, 611 (W.D.N.C. 2010) (precluding a party's expert witness from opining about a party's intent).

Moreover, to the extent that Dr. Garely's opinions are based on his review of documents that Plaintiffs' counsel selectively presented to him, these concern mere "lay matters which a jury is capable of understanding and deciding without the expert's help." *Andrews v. Metro N. Commuter R.R. Co.*, 882 F.2d 705, 708 (2d Cir. 1989).

This Court has precluded other plaintiffs' experts from offering similar testimony. In *Lewis v. Ethicon*, No. 12-cv-4301, 2014 WL 186872 (S.D. W. Va. Jan 15, 2014), this Court found that "expert opinions on Ethicon's knowledge or state of mind are not helpful to the jury" and that although plaintiffs' urogynecology expert Dr. Michael Margolis was "qualified as a physician; he is not qualified by 'knowledge, skill, experience, training or education' to opine on Ethicon's state of mind or knowledge." *Id.* at *15. In *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589 (S.D. W. Va. 2013), plaintiffs' urogynecology expert Dr. Bob Shull intended to testify about "Bard's knowledge, state of mind, alleged bad acts or failures to act, and corporate conduct and ethics." *Id.* at 610. This Court, however, found as follows:

> While an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions – assuming the opinions are otherwise admissible – *Bard's knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury* . . . . Accordingly, I FIND that Dr. Shull's opinions related to Bard's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics should be excluded.

Id. at *611 (emphasis added).

Most recently, this Court in *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 1718836, at *3 (S.D. W. Va., Apr. 28, 2016), held that "I will not permit the use of experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's knowledge, state of mind, or whether a party acted reasonably." This Court has continued to diligently adhere to these principles, directing counsel to "tailor expert testimony at trial" in accordance with these limitations. *Mathison v. Bos. Sci. Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *3 (S.D. W. Va. May 6, 2015).

For the same reasons that this Court previously precluded Dr. Margolis and Dr. Shull from testifying about such matters, the Court should also preclude Dr. Garely from testifying about these matters.

II. The Court should exclude Dr. Garely's opinions related to product warnings.

Dr. Garely offers numerous opinions regarding the alleged inadequacy of the Prolift and Prolift +M Instructions for Use (IFU), including his opinions that Ethicon failed to provide adequate information about potential contraindications of the Prolift kits in certain patient populations and that Ethicon knew about problems inherent to the Prolift kits and failed to warn physicians and patients of those problems. Exh. B, Rep. at 20-21. Examples of Dr. Garely's statements regarding the Prolift and Prolift +M IFUs include:

- In making an informed decision of whether or not to use a medical implant, the physician must be warned not only of the potential adverse events that may be associated with the product, but also of the frequency, severity, duration and potential permanence of adverse events. *Id.* at 22.

- Likewise, if a manufacturer knows that a complication can be chronic, severe or permanent, it should provide that information to those using its products. *Id.*

- Ethicon made representations in its Prolift IFU that Gynemesh PS had 'sufficient porosity for necessary tissue ingrowth,' and represented in its marketing materials that Gynemesh PS had 'Large pore size [which] fosters tissue incorporation.' *Id.* at 24.

- Despite being supplied this information by the director of the study, who also happened to be one of the inventors of the Prolift kits, Ethicon never provided any such warning or information to doctors nor indicated in the labeling any limitation on the use of the Prolift kits relative to the grade or severity of the prolapse. *Id.*

- Although Ethicon's corporate documents reflect that the amount of contraction or shrinkage associated with its polypropylene mesh implants was at least as high as 20% to 40%, and that this contracture is associated with deformation of the mesh and the tissues which can lead to chronic and unremitting pain, no warning has ever been provided by Ethicon about the frequency or severity of this increased risk. *Id.* at 25.

- In 2005, Ethicon's European Medical Director, Axel Arnaud, urged Ethicon to include the following warning in the Prolift IFU: 'WARNING: Early clinical experience has shown that the use of mesh through a vaginal approach can occasionally uncommonly lead to complications such as vaginal erosion and retraction which can result in anatomical distortion of the vaginal cavity that can interfere with sexual intercourse. Clinical data suggest the risk of such a complication is increased in case of associated hysterectomy. This must be taken in consideration when the procedure is planned in a sexually active woman.' No such warning was ever added to the Prolift IFU, and no warning addressing these recognized risks of anatomical distortion, interference with sexual intercourse, increased risk for hysterectomy, and avoidance of use in sexually active women was ever provided by Ethicon to doctors or patients. *Id.* at 26.

- A revised IFU for the Prolift kits put into effect on October 1, 2009 contained a vague statement about the [clinical study using the prototype]'s failure in the 'Clinical Performance' section, by noting of the study: 'met pre-defined criteria of upper limit of 90% CI less than 20% . . . no.' This unclear reference did not adequately convey to doctors that this clinical study failed to meet Ethicon's definition of successful prolapse treatment. *Id.*

- Moreover, Ethicon failed to warn physicians that this clinical study showed: a 75.6% adverse events rate; a 25.6% serious adverse event rate; a 10% 'severe' adverse event rate; a 50% rate of adverse events requiring treatment; and a 66.7% mesh-related adverse event rate. Ethicon never warned doctors of these complication rates, nor of the severity of these risks. *Id.* at 26-27.

- In a November 2008 PowerPoint, Ethicon's Medical Director, Piet Hinoul, urged the company to 'Inform! Mesh is permanent. Some complications may require additional surgery that may or may not correct the complication. Potential for

serious complications and their effect on quality of life: pain during intercourse, scarring, narrowing of the vaginal wall.' Ethicon never conveyed any such warning to doctors or to patients advising of these risks. *Id.* at 27.

- In an amended version of the Prolift kits' IFU released by Ethicon in October 2009, the company included a generic list of adverse events, including 'nerve damage,' but the company also prefaced the warning with the limiting language that 'Potential adverse reactions are those typically associated with surgery employing implantable materials of this type . . . .' This warning is inadequate and gives neither physicians nor their patients an indication that the Prolift mesh implant itself can cause damage, entrap, tether or sever nerves, and that this nerve damage can be difficult to treat or manage and that the complications may be permanent. *Id.*

- Ethicon failed to warn physicians and patients that the mesh arms on the Prolift would inevitably deform during and after implantation, which can inhibit proper tissue response and can cause or exacerbate pain, and can lead to painful mesh arm scarification (or 'banding'). Ethicon's Medical Director acknowledged that other than a generic reference to 'pain,' the specific risks of painful shrinkage, scarification and contraction of the mesh arms were not included in any warning. *Id.* at 27-28.

- Ethicon failed to adequately warn that the use of trocars inserted blindly through and into muscle and other tissue created the risks of tissue injury and potentially permanent nerve damage and pain. *Id.* at 28.

- Prior to October 1, 2009, Ethicon failed to provide any warning of the risks of voiding dyfunction, de novo incontinence, urinary tract infection or urinary obstruction or retention, following Prolift implantation. *Id.*

- It is extremely difficult to remove the Prolift mesh in its entirety once implanted, and even to remove parts of the mesh requires invasive surgery that few surgeons are qualified and able to properly perform. Ethicon failed to warn about this risk, and failed to provide any instruction or direction as to how to address complications, or what to do in the event mesh removal was necessary. *Id.*

Notwithstanding Dr. Garely's numerous assertions regarding inadequacies of the Prolift and Prolift +M IFUs, he cannot claim actual expertise in medical device warnings or labeling requirements.

A. Dr. Garely is not qualified to testify about product warnings.

Dr. Garely cannot credibly hold himself out to be an expert in products warnings. Although Dr. Garely claims to have been a member of the group that Ethicon asked to assist with developing the TVT and the IFU, as well as other educational materials, he conceded in his deposition that his experience had occurred twenty years earlier. Exh. C, Deposition of Alan Garely, M.D., dated April 15, 2016 ("Garely Tr.") at 37:5-42:4. Further, although he claimed to have "discussed things that belonged in the IFU" as a member of that group, he could not clarify what his involvement in the IFU had consisted of. *Id.* at 38:8-18. When asked if he had reviewed and provided feedback on the draft versions of the TVT IFU, he admitted that, "There were so many papers that we were looking at and formulating that to say that I specifically remember any one of those, I can't get my mind around that, no." *Id.* Dr. Garely's uncertain recollections of one experience with a different product category from twenty years prior cannot qualify him as an expert on labeling requirements.

Moreover, at his deposition, Dr. Garely admitted that he could not recall having ever reviewed either the FDA regulations relating to labeling and instructions for use; the FDA Blue Book Memo on what is required in an IFU; or Ethicon's standard operating procedures regarding what is required of IFUs. Exh. C, Garely Tr. at 40:5-42:4. Dr. Garely's assertion in his report that he has "reviewed numerous Instructions for Use . . . for a variety of medical products," Exh. B, Rep. at 6, does not make him an expert in medical device warnings; by this logic, any surgeon who has used medical devices and read the IFUs prior to use would be an expert in warnings.

When asked if he had reviewed regulatory guidances or regulations that address what the requirements of device labeling are, Dr. Garely conceded that if he had, it was "[o]nly in documents that I reviewed from internal documents" and "[w]hatever – from this case or from

the Bard case, when I had the internal documents from the companies." Exh. C, Garely Tr. at 39:12–40:4. Nor can he rely on actual use of the products at issue for an understanding of the risk of the devices, as he has never used Prolift or Prolift +M. *Id.* at 80:16-21. Thus, Dr. Garely's opinions as to the inadequacy of the Prolift and Prolift +M are based not on actual expertise but merely on the review of documents that Plaintiffs' counsel presented to him; a task that requires no expertise.

Ultimately, Dr. Garely acknowledged at his deposition that he could not identify any objective standard requiring product warning to contain information regarding the frequency, severity or permanence of potential complications:

> Q: . . . [M]y question is, can you point to any Federal regulation, guidance or other type of objective standard that requires Ethicon's IFU to include frequency, severity, duration and permanence information? Can you point to such a standard?
>
> A: As I sit here right now, I cannot point to it.

Exh. C., Garely Tr. at 217:7-14.

It is well established that an expert's qualifications must have a sufficient connection with the specific subjects at issue in the case. *See, e.g.*, *Free v. Bondo-Mar-Hyde Corp.*, 25 F. App'x 170, 172 (4th Cir. 2002) (affirming the exclusion of testimony because highly credentialed expert nevertheless lacked knowledge of specific matters essential to subject of his opinion).

Thus, in *C.R. Bard*, this Court precluded the plaintiffs' expert urogynecologist, Dr. Shull, from testifying about product warnings. 948 F. Supp. 2d at 612-13. Dr. Shull offered conclusory opinions about the defendant's product warnings, and he failed to "provide a reliable basis for his opinions of what Bard should have done with respect to its warnings." *Id.* at 611. According to the Court, "[t]his is likely the result of Dr. Shull's lack of expertise in the specific

area of warnings and labels for medical devices . . . ." *Id.* Accordingly, the Court concluded that "[d]espite his stellar qualifications as a urogynecologist, Dr. Shull is unqualified to testify on the specific issue of product warnings, as evidenced by his lack of familiarity with the process." *Id*. Here, as in that case, the Court should preclude Dr. Garely from testifying about product warnings, because it is outside his area of expertise.

B. Dr. Garely has not set forth reliable and trustworthy bases for his opinions.

Furthermore, many of Dr. Garely's statements regarding "complications" and "risks" set forth on pages 21-28 of Dr. Garely's Report, of which he asserts that Ethicon should have warned, are unreliable.

Dr. Garely makes blatantly false statements regarding Ethicon's dissemination of adverse event information "in its IFU as well as its training and marketing materials." Exh. B, Rep. at 22:

- Dr. Garely falsely states that, "Prior to October 2009, Ethicon failed to provide a warning addressing risks of nerve damage . . . ." Exh. B, Rep. at 27. The original Prolift IFU, published in 2004, warned that, "Punctures or lacerations of . . . nerves . . . may occur during GYNECARE PROLIFT Guide passage and may require surgical repair." Exh. D, 2004 Gynecare Prolift Information for Use, ETH.MESH.02341522-ETH.MESH.02341527 ("IFU") at 6.

- Dr. Garely's statement that "Prior to October 1, 2009, Ethicon failed to provide any warning of the risks of . . . urinary tract infection or urinary obstruction or retention, following Prolift implantation," Exh. B, Rep. at 28, also is false. The Surgeon's Resource Monograph ("Monograph"), published in April 2007, explicitly included "infection," "ureteral obstruction" and "urinary retention" in a list of the most notable complications. Exh. E, Prolift Surgeon's Resource Monograph ("Monograph") at 7.

- Dr. Garely also falsely states that "Between 2005 and 2009, Ethicon failed to warn doctors and patients of the risk of painful sexual intercourse (dyspareunia), mesh shrinkage, and that Prolift can cause pain that is chronic or permanent." Exh. B, Rep. at 25. To the contrary, the Monograph, issued in 2007, contains a detailed discussion of the risk of dyspareunia. Exh. E, Monograph at 9.

For other statements, Dr. Garely makes no attempt to provide any support. On page 25 of his Report, he states, "Ethicon's internal documents reflect that the pain experienced by Prolift (and Gynemesh PS) patients was specifically associated with the mesh, and thus is fundamentally distinct from the types of pain that may be 'associated with pelvic organ prolapse repair procedures.'" There is no citation or support for this assertion, and it should therefore be excluded. Dr. Garely also provides no support for his statement that "It is extremely difficult to remove the Prolift mesh in its entirety once implanted, and even to remove parts of the mesh requires invasive surgery that few surgeons are qualified and able to properly perform." Exh. B, Rep. at 28.

III. The Court should exclude Dr. Garely's opinions that amount to a mere historical commentary.

Many of Dr. Garely's opinions are also improper because they are nothing more than a cumulative historic commentary about Ethicon's alleged bad acts that have nothing to do with his expertise. As this Court has noted, such a rehashing of a fact narrative is improper. *Hines v. Wyeth*, 2011 WL 2680842, at *5 (S.D. W. Va. July 8, 2011) (Copenhaver, J.) (excluding expert testimony in part because it "merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness").

Such improper testimony includes Dr. Garely's opinions about Ethicon's alleged knowledge, state of mind, and product warnings, which the Court should also exclude for the reasons set forth above. Other examples of opinions beyond Dr. Garely's expertise that amount to an impermissible historical commentary include the following:

- **Ethicon withdrew the Prolift kits from the market rather than conduct safety and efficacy studies.** In 2011, the FDA assessed the safety and efficacy of Prolift as well as other pelvic organ prolapse available at the time, concluding that safety and efficacy had in fact not been shown. After the FDA made this determination, Ethicon withdrew their Prolift products from the market, as opposed to

conducting FDA-required clinical trials designed to assess the safety and effectiveness of the products. However, Ethicon internal documents and Ethicon-sponsored trials show that the safety risks associated with the Prolift kits exceeded any perceived benefit. Exh. B, Rep. at 6-7.

- Ethicon's corporate documents show that the company's consulting physicians had raised concerns about the safety profile of the Prolift. For example, around the time Ethicon launched the Prolift, Dr. Linda Cardozo, an Ethicon Prolift advisor, wrote the company to state: "I thought I would just let you know that I find the safety profile quite worrying and hope that this will be discussed in some detail especially in view of the fact that we have no efficacy data to review. It is not that there were a lot of complications, its severity and type of complications and these were just the peri operative ones! I still have major concerns regarding the erosion rate and possible problems with dyspareunia and none of these have been addressed in the data which we have been given to date." *Id.* at 8.

- Ethicon's European clinical trial failed to meet the internally determined criterion for successful prolapse treatment. In addition, Ethicon-sponsored clinical trials on Prolift and the mesh component in Prolift by Ethicon's consulting physicians resulted in high rates of serious complications caused by the product. This clinical information reflects the Prolift's unacceptable risk/benefit profile, which should have prevented Ethicon from bringing the product to market, or should have caused the company to withdraw the kits far sooner than it did. *Id.*

- Corporate documents generated after the launch of Prolift similarly reflect a lack of information about the compatibility of mesh with the female pelvis. *Id.* at 9.

- In 2006, Ethicon conducted cadaver labs in which an Ethicon consultant demonstrated that the Prolift mesh arms deform (or "crumple") upon implantation. These labs also produced photographic evidence of arm deformation with Prolift arms that were later included in several of Ethicon's internal documents explaining this phenomenon. *Id.* at 13.

There is no basis for Dr. Garely to rehash these alleged factual events, and his testimony should be excluded. *See United States v. Frazier*, 387 F.3d 1244, 1262-63 (11th Cir. 2004) ("Proffered expert testimony generally will not help the trier of fact when it offers nothing more than what lawyers for the parties can argue in closing arguments"); *In re Rezulin*, 309 F. Supp. 2d at 551 (excluding expert testimony intended merely to "provid[e] an historical commentary of what happened"); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (excluding portions of an expert's report because it "presents a narrative of select regulatory

events through the summary or selective quotation from internal Merck documents, regulatory filings, and the deposition testimony of Merck employees").

IV. The Court should exclude Dr. Garely's opinions related to FDA regulatory processes and requirements.

In his Report, Dr. Garely makes certain statements as to Ethicon's failure to comply with FDA regulatory processes and requirements, for example:

- **Ethicon disregarded governmental requirements in bringing the Prolift kits to market.** For over three years, Ethicon marketed and sold the Prolift kits (Prolift Anterior, Prolift Posterior, and Prolift Total, each of which represents both an Ethicon-marketed product and an Ethicon-marketed procedure), by bringing these products to market without FDA 510(k) clearance. Exh. B, Rep. at 6.

- **"Ethicon withdrew the Prolift kits from the market rather than conduct safety and efficacy studies.** In 2011, the FDA assessed the safety and efficacy of Prolift as well as other pelvic organ prolapse available at the time, concluding that safety and efficacy had in fact not been shown. After the FDA made this determination, Ethicon withdrew their Prolift products from the market, as opposed to conducting FDA-required clinical trials designed to assess the safety and effectiveness of the products. However, Ethicon internal documents and Ethicon-sponsored trials show that the safety risks associated with the Prolift kits exceeded any perceived benefit." *Id.* at 6-7.

However, as Dr. Garely admitted at his deposition, he is not a regulatory expert, and Plaintiff's counsel represented that Dr. Garely will not be offering an opinion as to whether Ethicon complied with FDA requirements or regulations in its sale or labeling of Prolift. Exh. C, Garely Tr., 153:19-157:5. As such, any statements by Dr. Garely regarding FDA regulatory processes and requirements should be excluded.

V. The Court should preclude Dr. Garely from rendering any opinion related to alleged degradation of mesh because he has admitted that it is not his opinion that polypropylene mesh degrades *in vivo*.

While his Report does make vague references to the alleged degradation of polypropylene, Dr. Garely made clear at his deposition that, unlike some of Plaintiffs' other experts, he does *not* hold the opinion that polypropylene mesh degrades in the body:

> Q: My question is, do you have an opinion to a reasonable degree of medical certainty that polypropylene mesh degrades within the body? That is not one of your opinions, is it, Doctor?
>
> A: No, it's not.
>
> Q: Certainly if you believe that, you wouldn't have implanted thousands of retropubic slings into women, correct?
>
> A: Correct.

Exh. C., Garely Tr. at 200:21-201:6.

To get around this, Dr. Garely approaches the degradation issue from a new angle, claiming that his opinion is that the statement in the Prolift IFU that the mesh is not "subject to degradation or weakening by the action of tissue enzymes" is not supported by the Ethicon documentation that Dr. Garely cites in his footnote. Exh. C, Garely Tr. at 201:7-17. However, given that he will not ultimately opine that the mesh degrades *in vivo*, then his opinion about the content of the IFU regarding degradation is irrelevant and should be excluded. In addition, the Court should exclude any opinion of Dr. Garely regarding alleged degradation for the reasons set forth in the Point below.

VI. The Court should preclude Dr. Garely from rendering an opinion on biomaterial properties of mesh, alleged nerve entrapment, alleged degradation or the design of medical devices.

The Court should preclude Dr. Garely from rendering opinions on biomaterials, polypropylene degradation, entrapment of tiny nerves in mesh pores, chronic foreign body reaction, adequate pore size, adequate weight of polypropylene, and biocompatibility of polypropylene. Dr. Garely's Report touches upon all of these topics, and opine on the way in which a synthetic material interacts with living tissues—*i.e.*, the subject of biomaterials science. Indeed, Dr. Garely is not qualified by education, training or experience to opine on biomaterials science issues, including, without limitation, polypropylene mesh degradation, collapse, and

porosity. As Dr. Garely admitted at his deposition, Dr. Garely is not a biomaterials engineer, a polymer scientist or pathologist. Exh. C, Garely Tr. at 36:5-12. He also has never looked at the mesh in Prolift or Prolift +M under a microscope, performed any animal studies on either kind of mesh, or performed any benchtop testing on either kind of mesh or on the tools for either product. *Id.* at 86:2-87:3. Nothing else in Dr. Garely's experience as a surgeon would inform, for example, his opinion that the mesh in Prolift or Prolift +M, degrade in the human body or result in a "biomechanical mismatch between the implant and the pelvic tissues." Exh. B, Rep. at 9.

Dr. Garely's opinions on alleged nerve entrapment in mesh are a perfect example of where his opinions extend considerably beyond his expertise. In his Report, Dr. Garely opines that the process of contraction causes the tissue surrounding the implanted mesh to entrap tiny nerves, causing chronic pain. Exh. B, Rep. at 11; Exh. C, Garely Tr. at 182:16-183:20. However, Dr. Garely is not trained in the processes required to make such a pathological assessment. At his deposition, Dr. Garely agreed that in order to investigate whether mesh explants had evidence of entrapped nerves, the mesh would need to be examined under a microscope, which he has never done. Exh. C, Garely Tr. at 185:5-13. However, not only is he not a pathologist, but he has not even received training in how to interpret what is seen under a microscope since taking histology and pathology in residency 26 years ago. *Id.* at 185:16-186:6. He acknowledged that if a mesh slide was provided to him, he would need the assistance of a trained pathologist to properly and reliably interpret what could be viewed under the microscope. *Id.* at 186:7-19 ("I'm not really good at looking at tiny nerves under the microscope.") He does not use microscopes in the treatment of his patients, including the treatment of patients with mesh complications. *Id.* at 186:20-187:3. Nor does he know what stains or magnifications

would be required to perform such an analysis. *Id.* at 187:4-14. For these reasons, Dr. Garely should not be permitted to testify regarding alleged nerve entrapment in mesh.

Likewise, in other mesh litigation, the proffered experts' qualifications to opine about biomaterial properties such as degradation and porosity have been closely scrutinized and such testimony has been limited to experts with extensive biomaterial and biomechanical engineering education and experience. *See In re C.R. Bard*, 948 F. Supp. 2d at 623 (allowing physician testimony regarding biomechanical analysis of mesh only after establishing that physician had two engineering degrees, had practiced as an engineer for twelve years, and had focused on studying biomechanical analysis of pelvic floor structures and the pelvic floor from an engineering perspective for ten years); *id.* at 633 (expressing "concerns about [physician's] qualifications to testify specifically as to the properties of polypropylene" mesh, but allowing testimony only after establishing that physician not only had a biomedical engineering degree, but also routinely evaluated biomaterials, developed new biomaterials and modified existing biomaterials, and had specific experience with polymeric material). In the present case, Dr. Garely' lack of biomaterials expertise precludes him from testifying about the biomechanical properties of mesh.

Additionally, Dr. Garely has no particular medical device design expertise that would otherwise qualify him to opine that "[t]he Prolift is defectively designed." Exh. B, Rep. at 7. Dr. Garely admitted at his deposition that he does not hold himself out as an expert in FDA regulations on design controls, and he could not testify as to having knowledge of what information is required in an FMEA or DDSA. Exh. C, Garely Tr. at 36:5-12, 42:20-23, 45:1-10. Although Dr. Garely testified that he provided product feedback and input into training materials for TVT two decades ago, *id.* at 37:20-38:11, this single experience two decades ago

does not qualify him as an expert on the design of Prolift and Prolift +M. There is no evidence that he has designed a mesh-based prolapse repair device, and he has not published any articles about mesh device design. Exh. B, Rep. at 3-5. Accordingly, his opinions regarding design defect amount to speculation and should be excluded.

In addition to Dr. Garely's lack of qualifications to opine on such issues, he also employs an unreliable methodology by basing his material opinions nearly entirely on his personal experience with only 10-20 mesh explants and his review of internal company documentation. Reliance on peer-reviewed medical literature is almost entirely absent from the portions of his Report on these opinions. In particular, Dr. Garely was unable to identify any peer-reviewed medical literature supporting his opinions that:

- The pores of Prolift mesh deform or distort after implantation. Exh. C, Garely Tr. at 179:19-182:15.
- Tissue integration causes an "asymmetrical pulling" on the arms of the mesh which causes roping and curling of the mesh. *Id.* at 197:19-198:4.
- The statement in the Prolift IFU that the mesh is not "subject to degradation or weakening by the action of tissue enzymes" is not supported by the Ethicon documentation that Dr. Garely cites in his footnote. *Id.* at 198:13-200:7.
- Pelvic pain and dyspareunia following Prolift is permanent and not treatable. *Id.* at 229:20-232:22.

Dr. Garely should not be permitted to offer these opinions to a jury in the absence of peer reviewed medical literature that reinforces his personal opinions and his interpretation of company documents.

VII. The Court should preclude Dr. Garely from rendering any opinions regarding alleged safer alternative designs that have no reliable basis.

Dr. Garely makes assertions regarding "safe feasible alternative designs" that were available to Ethicon. However, none of the purported "alternatives" he proposes constitutes a

safer alternative design, and all such statements by Dr. Garely should be excluded. Dr. Garely asserts that the following are "alternatives" to the Prolift and Prolift +M: "native tissue repairs, or non-surgical pelvic organ prolapse treatments like Kegel exercises and pessaries" as well as "elimination of the mesh arms; elimination of the armed, blind trocar implantation design; possible use of alternative materials, such as biologic materials or polyvinylidene fluoride (PVDF/Pronova)." Exh. B, Rep. at 29.

Native-tissue repairs, Kegel exercises and pessaries are alternate methods of treatment, not alternative designs, and thus these statements should be excluded. The "elimination" alternatives proposed by Dr. Garely also are not safer, feasible alternative designs, but rather abstract notions. Dr. Garely was clear at his deposition that it is his opinion that no mesh should be placed transvaginally to treat prolapse. Exh. C, Garely Tr. at 73:17-74:1. Accordingly whether a mesh implant has arms or is placed through a blind trocar passage is ultimately irrelevant to his opinion and should be excluded. *Id.* at 72:2-16. Dr. Garely also admitted at his deposition that he does not use biologic materials for prolapse repair, *id.* at 50:4-12, and use of these materials constitutes an alternate treatment method, not a safer alternative design.

As to polyvinylidene fluoride/PVDF/Pronova, as Dr. Garely conceded at his deposition, they are not commercially available, Exh. C, Garely Tr. at 206:20-22, and therefore cannot be a safer alternative design; moreover, even if this material were available in the U.S., Dr. Garely testified that he "would not" use it in his patients. *Id.* at 221:18-21. Dr. Garely has admitted that he has seen no clinical literature assessing the use of PVDF as an implant to treat prolapse and would need to see such evidence before he ever implanted PVDF in his patients. *Id.* at 209:2-9; 221:19-222:6. Rather, his entire basis for offering PVDF as an alternative safer design is his review of internal company documents where Ethicon employees discussed the theoretical

possibility of using PVDF in vaginal indications; indeed, at his deposition, Dr. Garely admitted that he was "just restating what was stated in internal documentation." *Id.* at 207:24-209:19. This is not a reliable methodology for proposing an alternative safer design. And as previously recognized by this Court, mere regurgitation of company documents is not a proper basis for expert testimony as it does not provide further assistance to the jury. *Hines*, 2011 WL 2680842, at *5.

CONCLUSION

For the reasons set forth above, the Court should limit the parameters of Dr. Garely's testimony consistent with the foregoing.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 5, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Kelly S. Crawford
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